AMENDED IN ASSEMBLY JANUARY 6, 2010 AMENDED IN ASSEMBLY JANUARY 4, 2010 AMENDED IN ASSEMBLY APRIL 23, 2009 AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 977

Introduced by Assembly Member Skinner

February 26, 2009

An act to amend Section 4052 of, and to add and repeal Section 4052.8 to, of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 977, as amended, Skinner. Pharmacists: immunization protocols with physicians.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime. Existing law, among other things, authorizes a pharmacist to administer immunizations pursuant to a protocol with a prescriber.

This bill, *until January 1, 2015*, would additionally authorize a pharmacist to initiate and administer influenza—and pneumococcal immunizations to any person—11 18 years of age or older pursuant to standardized protocols developed and approved by both the board and the Medical Board of California. The bill would require a pharmacist, prior to initiating and administering those immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist initiating and administering

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those immunizations to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require a pharmacist, at the time of administration of an that immunization, to provide the patient with a Vaccine Information Statement and to provide the patient and the patient's physician with documentation of administration of the immunization. The bill would also require a pharmacist administering an that immunization to maintain a specified immunization record, provide documentation of administration to the appropriate immunization registry, report any adverse event and assure ensure proper storage and handling of vaccines. The bill would authorize a pharmacist initiating and administering vaccines under these provisions to initiate and administer epinephrine for severe allergic reactions. The bill would also require a pharmacist to obtain the consent of a parent or guardian before administering any immunization to a patient under 18 years of age.

This bill would require the board and the Medical Board of California to complete an evaluation of influenza immunizations initiated and administered under the standardized protocols authorized by the bill, and to report to the appropriate policy committees of the Legislature by January 1, 2014.

Because this bill would create new requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the 2 following:
- 3 (a) Vaccines are a safe, effective, and efficient means to prevent
- 4 sickness and death from infectious diseases as reported by the
- 5 United States Department of Health and Human Services (HHS).

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(b) The National Vital Statistics Report published by HHS reports that influenza and pneumonia combined are the eighth leading cause of death in people of all ages, and the sixth leading cause of death in people over 65 years of age.

(c)

(b) The federal Centers for Disease Control and Prevention report that 220,000,000 persons should get the influenza vaccination annually, however, fewer than 100,000,000 do.

9 (d)

(c) According to the California Health Care Foundation, 6,600,000 Californians are uninsured and may not have access to immunizations.

(e

(d) Pharmacists represent the third largest health professional group in the United States and are on the front line of preventative care.

17 (f)

(e) Pharmacists are trained to screen, administer, and properly deal with any adverse events that may arise from vaccines.

(g)

(f) Primary care physicians play an integral role in preventative health care for Californians. This act will provide an adjunct to that preventative health care.

(h)

- (g) Therefore, in order to achieve greater access to immunization and to protect Californians, it is the intent of the Legislature to provide greater access to lifesaving vaccinations and to ensure that pharmacists may—independently administer influenza—and pneumococcal vaccinations.
- SEC. 2. Section 4052 of the Business and Professions Code is amended to read:
- 4052. (a) Notwithstanding any other provision of law, a pharmacist may:
- (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
 - (2) Transmit a valid prescription to another pharmacist.
- (3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.
- 39 (4) Perform procedures or functions in a licensed health care 40 facility as authorized by Section 4052.1.

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 (5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

- (6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.
- (7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.
- (8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.
 - (9) Administer immunizations pursuant to Section 4052.8.
- (b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.
- (c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.
- (d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility. SEC. 3.
- SEC. 2. Section 4052.8 is added to the Business and Professions Code, to read:
 - 4052.8. (a) A pharmacist may do either of the following:
- (1) Administer any immunization pursuant to a protocol with a prescriber.
- (2) Administer initiate and administer influenza—and pneumococcal immunizations, pursuant to standardized protocols developed and approved by both the board and the Medical Board of California in consultation with public health officers, to any person—11 18 years of age or older. The standardized protocols shall be consistent with protocols developed by the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.
- 38 Disease Control and Prevention.
- 39 (b) Prior to initiating and administering immunizations, a 40 pharmacist shall complete the American Pharmacists Association's

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- 1 Pharmacy-Based Immunization Delivery Certificate Training
- 2 Program or another pharmacy-based immunization training
- 3 certificate program endorsed by the federal Centers for Disease
- 4 Control and Prevention or the Accreditation Council for 5 Pharmaceutical Education.
 - (c) (1) A pharmacist initiating and administering any immunization pursuant to this section shall also complete three hours of immunization-related continuing education coursework annually.
 - (2) If a pharmacist fails to satisfy this requirement, he or she shall, in addition to any other applicable disciplinary action, retake the training identified in subdivision (b) and also complete the three hours of immunization-related continuing education coursework described in paragraph (1) prior to initiating and administering any further immunizations.
 - (3) The three hours of immunization-related continuing education may be applied toward the continuing education requirement described in Section 4231.
 - (d) A pharmacist initiating and administering any immunization pursuant to this section shall at all times be certified in basic life support.
 - (e) For any patient under 18 years of age, a pharmacist shall obtain the consent of a parent or the patient's guardian before administration.

(f)

- (e) At the time of administration of an immunization, the pharmacist shall do all of the following:
- (1) Provide the patient or the patient's agent with the appropriate Vaccine Information Statement, produced by the federal Centers for Disease Control and Prevention, for each immunization administered.
- (2) Provide documentation of administration of the immunization to the patient and the patient's physician or primary care provider, if one can be identified.
- (3) Provide documentation of administration of the immunization to the appropriate immunization registry.

(g)

(f) The pharmacist shall maintain an immunization administration record, which shall include, but not be limited to, the name of the vaccine, the expiration date, the date of

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administration, the manufacturer and lot number, the administration site and route, the Vaccine Information Statement date, and the name and title of the person administering, for-the longer of the following periods:

- (1) Ten years from the date of administration.
- (2) If the patient is younger than 18 years of age at the time of administration, three years beyond the patient's 18th birthday. 10 years from the date of administration.

(h)

(g) Any pharmacist initiating and administering vaccines may initiate and administer epinephrine by injection for severe allergic reactions.

(i)

(h) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the United States Department of Health and Human Services.

(j)

- (i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible for assuring ensuring that proper vaccine temperatures are maintained during subsequent storage and handling to preserve the potency of the vaccine.
- (j) The board and the Medical Board of California shall evaluate the effectiveness of the initiation and administration of immunizations pursuant to this section, and report to the appropriate policy committees of the Legislature by January 1, 2014.
- (k) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.
- SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

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